IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	
Ronald J. JANDACEK et al.	:	Confirmation No. 9438
Serial No.: 10/567,143	:	Group Art Unit: 1797
I.A. Filing Date: 08/05/2004	:	Examiner: WALLENHORST, Maureen

Title: USE OF NON-ABSORBABLE FAT IN DETERMINING DIETARY FAT ABSORPTION

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Ronald J. Jandacek, do hereby declare as follows:

1. I am a joint inventor under the subject matter described and claimed in the above-identified patent application.

2. I hold an undergraduate degree in chemistry from Rice University and a PhD in physical chemistry from the University of Texas at Austin.

3. I have been conducting research in dietary fats and nondigestible fat materials since 1972. I previously worked for The Procter & Gamble Company from 1968 to 2001, attaining the position of Research Fellow in the areas of foods and pharmaceuticals. I am currently employed in research in the Department of Pathology and Laboratory Medicine, in the College of Medicine of the University of Cincinnati. In these two positions, as shown on the attached curriculum vitae, I am an author on numerous peer-reviewed publications and inventor on numerous patents in the area of lipid metabolism.

4. I have read and am familiar with the Office Action in the present application issued on April 16, 2009, and with the publication reference of Janghorbani et al.

5. Janghorbani et al. describe the measurement of a labeled dietary fat (such as a C^{13}-labeled palmitin) and a lanthanide salt as a non-digestible marker in a colored stool sample from a patient, in order to measure fat digestion and absorption. A labeled fat would have lipophilic properties. A lanthanide salt is an inorganic compound that is not soluble in lipids. Janghorbani et al describe that the certain lanthanide salt ($DyCl_3$) and labeled triglyceride follow the same excretion kinetics, which to me would only mean that the materials pass through the digestive system at about the same relative rate.

6. In my opinion, the lanthanide salt and any labeled fat would not be miscible or homogenous in the patient's stool, and a person of ordinary skill in the art would expect, from the disparity in physical properties between fat (a lipid) and lanthanide salt (an inorganic salt that is not soluble in lipid), that these two materials would not disperse homogenously in the stool, thus necessitating the collection and homogenizing of the entire stool before taking a sample for analysis.

7. Janghorbani et al describe that "(e)ach stool was transferred to a tared plastic container and weighed accurately" (col 6 lines 6-7). I understand this to say that the entire stool of the patient was collected, and the entire weight of stool obtained. Janghorbani et al also describes that "the stool is homogenized and a weighed fraction taken for analysis". I understand this to say that the entire stool of the patient is first homogenized, and then a portion of the homogenized material is taken for analysis. This technique would be completely consistent with the lanthanide salt and the labeled fat being immiscible or segregating from one another within the fecal material.

8. The advantage provided in Janghorbani et al relates to the convenience of coloring the stool so that only a stool that is colored needs to be collected, and to the sampling for analysis of only a small portion of the homogenized colored stool. Janghorbani et al does not disclose collection of only a small portion of the stool from the patient, from which the sample is

taken, and does not suggest that the method is effective for determining fat absorption without homogenizing the entire stool sample before analysis.

9. As a person of skill in the art, I recognized that a marker used for studying fat absorption using small fecal samples that are not homogenized, was required to be non-absorbable and non-digestible, but was also required to be co-localizable or miscible with the dietary fat in the stool sample. Janghorbani et al failed to identify this important characteristic which is provided by the sucrose behenate in the method claimed in the present application.

10. On the contrary, the Applicants' specification describes that dietary fat and sucrose polyester (including sucrose behenate) have the same physical properties (para. [0030], lines 6-7, and para. [0033] lines 7-11), and because dietary fat and sucrose behenate are inherently soluble and miscible in one another, the claimed method enables the collecting of just a small portion of the stool from a subject as a sample, without requiring homogenizing.

I further declare that all statements made of my knowledge are true and that all statements made on information and belief are believed to be true; further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 USC 1001 and may jeopardize the validity of the application or any patent issuing thereon.

October 14, 2009
Date

Ronald J. Jandacek

18 USC 1001: *"Whoever in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both."*

CURRICULUM VITAE

PERSONAL INFORMATION

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U.S. Citizen
Born December 26, 1942, in Chattanooga, Tennessee
Married to Jane Parker Jandacek
Four children: Christopher, born January 1, 1968
Margaret, born November 18, 1969
Emily, born December 29, 1984
Lillian, born December 29, 1984

EDUCATION

B. A. Chemistry, cum laude, Rice University, 1964
Ph.D. Chemistry, University of Texas at Austin, 1968

EMPLOYMENT

Procter & Gamble, Miami Valley Laboratories, 1968
U.S. Army, Walter Reed Army Institute of Research, 1968-69
U.S. Army, Armed Forces Institute of Pathology, 1969-70
Procter & Gamble, Miami Valley Laboratories, 1970-2001
University of Cincinnati, Adjunct Professor, Department of Pathology, 2001-present

PROFESSIONAL MEMBERSHIPS

American Chemical Society, American Oil Chemists' Society, American Society for Nutritional Sciences

PUBLICATIONS

1. Shoulders BA, Gipson RM, Jandacek RJ, Simonsen SH, Shive W. Conformation and biological activity of 1,4-Cyclohexadiene derivatives, J. Am Chem Soc. 90: 2294-2295 (1968).
2. Jandacek RJ, Simonsen SH. The crystal structure of 1,4-cyclohexadiene-1-glycine. J Am Chem Soc 91: 6663-6665 (1969).
3. Swartz HM, Richardson EC, Copeland ES, Jandacek RJ. Structure-function studies of the aminothiol radioprotectants. in Radiation Protection and Sensitization (Moroson and Quintiliani, ed.), Taylor and Francis, 121-131, London (1970).
4. Jandacek RJ, Swartz HM. The conformation of radioprotectant compounds. Radiat Res 44: 523-530 (1970).
5. Jandacek RJ, Earle KM. The crystal structure of L-DOPA hydrochloride. Acta Cryst, B27, 841-845 (1970).

6. Curry JD, Jandacek RJ. Synthesis and crystal structure of bis(1-oxopyridine-2-thiolato)phenyl-bismuth. J Chem Soc Dalton, 1120-1123 (1972).
7. Mattson FH, Jandacek RJ, Webb MR. The effect of a nonabsorbable lipid, sucrose polyester, on the absorption of dietary cholesterol by the rat. J Nutr, 106: 747-752 (1976).
8. Uchtman VA, Jandacek RJ. The crystal and molecular structure of tetrasodium carbonyl diphosphonate. Acta Cryst B32: 488-492 (1976).
9. Jandacek RJ, Webb MR, Mattson FJ. Effect of an aqueous phase on the solubility of cholesterol in an oil phase. J Lipid Res. 18: 203-210 (1977).
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13. Volpenhein RA, Webb DR, Jandacek RJ. The effect of nonabsorbable lipid, sucrose polyester, on the absorption of DDT by the rat. J Tox and Environ Health, 6: 679-683 (1980).
14. Glueck CJ, Jandacek RJ, Subbiah MTT, Gallon L, Yunker R, Allen C, Hogg E. Effect of sucrose polyester on fecal bile acid excretion in normal man. Am J Clin Nutr 33: 2177-2181 (1980).
15. Uchtman VA, Jandacek RJ. Structural investigations of calcium binding molecules. 5. Structure analysis of a calcium salt of benzene hexacarboxylic acid (Mellitic acid), $Ca_2C_2H_2O_{12}9H_2O$. Inorg Chem 19: 350-355 (1980).
16. Jandacek RJ, Bohne RL. The removal of organic substances from water with nonvolatile edible solvents. J Am Oil Chem Soc 55: 705A-706A, (1980).
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63. McNamara RK, Hahn CG, Jandacek R, Rider T, Tso P, Stanford KE, Richtand NM. Selective deficits in the omega-3 fatty acid docosahexaenoic acid in the postmortem orbitofrontal cortex of patients with major depressive disorder. Biol Psychiatry 62: 17-24 (2007)
64. McNamara RK, Jandacek R, Rider T, Tso P, Hahn CG, Richtand NM, Stanford KE. Abnormalities in the fatty acid composition of the postmortem orbitofrontal cortex of schizophrenic patients: gender differences and partial normalization with antipsychotic medications. Schizophr Res (2007).
65. Jandacek RJ, Tso P. Enterohepatic circulation of organochlorine compounds: a site for nutritional intervention. J. Nutr Biochem 18:163-167 (2007). Review. Erratum in: J Nutr Biochem. 2007 May;18(5):355 (2007).
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70. McNamara RK, Liu Y, Jandacek RJ, Rider T, Tso P. The aging human orbitofrontel cortex: Decreasing polyunsaturated fatty acid composition and associated increases in lipogenic gene expression and stearoyl-CoA desaturase activity. Prostagland Leukot Essent Fatty Acids78: 293-304 (2008).
71. Lo CM, Samuelson LC, Chambers JB, King A, Helman J, Jandacek RJ, Sakai RR, Benoit SC, Raybould HE, Woods SC, Tso P. Characterization of mice lacking the gene for cholecystokinin. Am J Physiol Regul Integr Comp Physiol 294: R803-810 (2008).
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79. McNamara RK, Able J, Jandacek R, Rider T, Tso P, Lindquist DM. Perinatal omega-3 fatty acid deficiency Selectively reduces myo-inositol levels in the adult rat prefrontal cortex: An in vivo proton magnetic resonance spectroscopy study. J Lipid Res 2008 Sep
80. McNamara RK, Jandacek R, Rider T, Tso P, Stanford KE, Hahn CG, Richtand NM. Deficits in docosahexaenoic acid and associated elevations in the metabolism of arachidonic acid and saturated fatty acids in the postmortem orbitofrontal cortex of patients with bipolar disorder. Psychiatry Res 2008 Sep
81. McNamara RK, Sullivan J, Richtand NM, Jandacek R, Rider T, Tso P, Campbell N, Lipton J. Omega-3 Fatty acid deficiency augments amphetamine-induced behavioral sensitization in adult DBA/2J mice: relationship with ventral striatum dopamine concentrations. Synapse 62: 725-735 (2008).
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BOOK CHAPTERS

1. R. J. Jandacek. "Commercial applications of fatty acid derivatives in foods." in Saturated and Unsaturated Fatty Acids in Foods, C. Chow, ed., Marcel Dekker, 2007.
2. R. J. Jandacek, Food Fats and Health, Council for Agricultural Science and Technology, Task Force Report 18, December 1991.
3. Tso, P. and Jandacek, R. J. "Lymph, Lymphatics, and Lymph Flow." In Encyclopedia of Gastroenterology, Elsevier, 2004.

AWARDS

Division Technical Excellence Award - Food & Beverage Technology Division - 5/19/92.

Cincinnati Section of the American Chemical Society. Chemist of the Year Award - 3/15/95.

PRESENTATIONS

American Oil Chemists' Meeting, September 1976, Chicago, IL "Sucrose Polyesters: Unabsorbable, Cholesterol-Lowering Fat"

Invited speaker, Hugh Lofland Conference on Arterial Wall Metabolism, May 1977, Portland, OR

"Solution Properties and Absorption"

Invited speaker, Michigan State Symposium on Polybrominated Biphenyls, June 1980, Michigan State University "Effects of Sucrose Polyester on Lipophile Absorption"

VII International Symposium on Drugs Affecting Lipid Metabolism, June 1980, Milan, Italy

"The Effect of Sucrose Polyester on the Absorption of DDT"

Invited speaker, Symposium on Metabolism and Pharmacokinetics of Environmental Chemicals in Man, June 1981, Sarasota, FL "The Effect of Nonabsorbable Lipids on the Intestinal Absorption of Lipophiles"

Invited speaker, Harvard Medical School, Department of Biological Chemistry, June 1981, Boston, MA "Studies with Sucrose Polyester"

Society of Toxicology Meeting, March 1983, Las Vegas, NV "SPE Stimulates Fecal Excretion of DDT in Gerbils" (co-author)

Invited speaker, Symposium on Food in Contemporary Society, May 1983, Knoxville, TN

"Studies with Sucrose Polyester, A Nonabsorbable Fat"

University of Minnesota, September 1983, Minneapolis, MN "Studies with Sucrose Polyester, A Nonabsorbable Lipid"

Invited speaker, International Congress on Obesity, October 1983, New York, NY

"Studies with Sucrose Polyester, A Nonabsorbable Lipid"

Research Associates of Dept. of Chemistry, June 1983, U. Cincinnati, Cincinnati, OH

"Studies with Sucrose Polyester"

Invited speaker, S. Carolina Nutrition Council, June 1984, Columbia, SC "Studies with Sucrose Polyester"

Cornell University Dept. of Food Science, April 1985, Ithaca, NY "Studies with Sucrose Polyester"

Invited speaker, American Chemical Society Symposium on Dietetic and Pharmacodynamic Lipids, April 1985, Miami, FL "Studies with Sucrose Polyester"

Invited presentation. Northwest regional meeting of the American Oil Chemists' Society. University of Massachusetts, Amherst, Mass. Studies with olestra. April 10, 1989.

Invited presentation. American Chemical Society national meeting, Miami, Florida. The properties of olestra, a unique fat substitute. September 12, 1989.

Lecture at Specialty Fats Short Course. American Oil Chemists' Society national meeting, Cincinnati, OH May 2, 1989.

Presentation at Pacifichem meeting. The development, properties, and utilization of olestra, a nonabsorbable fat substitute. Honolulu, December 19, 1989.

Presentation on olestra to Washington D.C. chapter of IFT, March 1990.

Presentation on olestra to Ohio Academy of Sciences meeting, Dayton, OH April 1990.

Lecture at Institute of Food Technologists' Short Course on Food Ingredients, "Fats and Oils." Anaheim CA June 1990; New Brunswick NJ, Nov. 1990; Atlanta GA Feb. 1991.

Invited presentation to International Business Communications Symposium, New Orleans, Apr. 1992 "Nutritional Properties of Synthetic Fats."

Invited presentation Purdue, Department of Nutrition, Apr. 1992 -"Nutritional Properties of Synthetic Fats."

Invited presentation, Ohio State University, Department of Nutrition, May. 1992 -"Nutritional Properties of Synthetic Fats."

Invited presentation. Institute of Medicine of the National Academy of Sciences workshop: An Evaluation of Potential Performance Enhancing Food Components for Operational Rations. Washington, D.C., November 1992. "Structured Lipids: An Overview and Comments on Performance Enhancement Potential."

Invited presentation. FASEB Summer Conference on Intestinal Lipid Absorption, Metabolism, and Transport. Saxton's River, Vermont, August, 1994.

Invited presentations. Notes of a Fat watcher: March 1995, Cincinnati American Chemical Society; 1996 University of Cincinnati College of Medicine; University of West Virginia; Western Kentucky University; Vanderbilt University; University of Nebraska, American Chemical Society National meeting, Orlando; 1997, Michigan State University.

Invited presentation. U.S. Army conference on nutrients, Natick, MA 2004

Invited presentation University of Kentucky, Dept. of Toxicology Seminar, February 14, 2005

Invited presentation University of Kentucky, Symposium on Nutrition and Superfund Chemicals, November 18, 2005

Invited presentation, PCB Workshop, Zakopane, Poland, September 6-10, 2006

PATENTS

U.S. 3,865,939	Edible Oils Having Hypocholesterolemic Properties
U.S. 4,005,195	Compositions for Treating Hypercholesterolemia
U.S. 4,005,196	Vitamized Compositions for Treating Hypercholesterolemia
U.S. 4,241,054	Detoxifying Lipophilic Toxins
U.S. 4,264,583	Gallstone Dissolution Compositions and Method
U.S. 4,797,300	Compositions Containing Novel Solid, Nondigestible, Fat-Like Compounds
U.S. 4,753,963	Nutritional fat suitable for enteral and parenteral products.
U.S. 4,948,811	Salad/cooking oil balanced for health benefits.
U.S. 5,017,398	Tetrabehenyl tetracapryl sucrose as substitute for saturated fat in margarine.
U.S. 7,025,984	Compositions and methods for body weight management.

Member of Editorial Board of *Physiology and Behavior*

JOURNAL REFEREE FOR: J. Lipid Research; Lipids; J. American Oil Chemists' Society; Biochem. Biophys. Acta.; J. Nutrition; Physiology and Behavior; Pediatric Research; American Journal of Physiology; British Journal of Nutrition; Future Lipidology; Chemical-Biological Interactions; Biomarkers in Medicine; Journal of Medicinal Food; Toxicology and Applied Pharmacology;Translational Research.

FUNDING

SUPPORT

Jandacek, Ronald PHD

ACTIVE:

5 R01 HL 62542-09 (PI: Davidson) 4/1/2004 – 3/31/2009 .6 cal
NIH/NHLBI $175,000
"Mechanisms of apolipoprotein-mediated cholesterol efflux."

The major goal of this project is to define the molecular basis of the interaction between ABCA1 and apolipoprotein A-I during apolipoprotein-mediated cholesterol efflux.

5 U01 ES012770-05 (Robert Bornschein, PI) 9/29/2003-7/31/2010 .72 cal
NIH/ES $969,269/yr
"Puberty & Cancer initiation: Environment, Diet, and Obesity"

The objective of this research is to determine the relationships between diet (especially fatty acid and phytoestrogen consumption) and exposure to environmental toxins during the prenatal period and childhood on level of adiposity and consequently the pathway through puberty, which may be either drive primarily by the adrenal gland (adrenarche) or ovaries (thelarche).

5P01 DK56863-07 (Stephen Woods, PI) 5/1/2006 – 4/30/2011 1.2 cal
NIH/NIDDK *$798,026/yr*
"High Fat Diet-Induced Obesity"

This project will investigate the mechanisms that cause obesity in individuals consuming a high-fat diet.

1 R01 ES014464-A2 (Tso, PI) 11/1/2007 – 10/31/2011 3.0 cal
NIH/ESO *$250,000/yr*
"Interaction of Nutrient & Organochlorine Absorption"

This project will investigate the absorption and transport of organochlorines in lymph and blood to better understand the ways in which nutrients influence the absorption processes.
This project will explore the possibility that several transport proteins, CD36, SR-BI, and NPC1-L1, differing in intracellular location as well as in different parts of the small intestine may play an integral role in the uptake and transport of cholesterol.

OVERLAP:
None

PENDING:
None